PMA Decisions Rendered for August 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
PMA Original Approvals			
P050024 **8/1/07**	CryoCor CryoAblation System	CryoCor, Inc. San Diego, CA 92121	Approval for the CryoCor CryoAblation System. The device is indicated for use in the ablation of isthmus-dependent right atrial flutter in patients 18 years of age or older.
P050043 **8/20/07**	Femoral Introducer Sheath and Hemostasis (FISH™) Device 5,6, and 8 French	Morris Innovative research, Inc. Bloomington, IN 47403	Approval for the Femoral Introducer Sheath and Hemostasis (FISH™) device 5, 6, and 8 French. The device is indicated as follows: The Femoral Introducer Sheath and Hemostasis (FISH™) device is intended for hemostatic closure of femoral artery access sites. The system is indicated for use in reducing time to hemostasis and time to ambulation in patients who have undergone diagnostic procedures using 5, 6, or 8 French procedural sheaths.
PMA Supplemental Approvals			
P790017/S086 **8/17/07** **135-Day**	Gruntzig Dilaca Coronary Artery Balloon Dilatation Catheter	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval to: 1) introduce an automated inflation device, replacing the current manual process, to inflate PTCA balloons prior to in-process functional testing; and 2) reduce the number of samples which are taken to monitor particulate levels in nitrogen gas and compressed air.
P880003/S089 **8/29/07** **180-Day**	DURA STAR™ Rx PTCA Dilatation Catheter	Cordis Corporation Warren, NJ 07059	Approval for a new catheter model. The device, as modified, will be marketed under the trade name DURA STAR™ Rx PTCA Balloon Dilatation Catheter and is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. In addition, the DURA STAR™ Rx PTCA Dilatation Catheter is indicated for post-delivery expansion of balloon expandable stents.
P880003/S090 **8/31/07** **180-Day**	FIRE STAR™ Rx PTCA Dilatation Catheter	Cordis Corporation Miami Lakes, FL 33014	Approval for a new catheter model. The device, as modified, will be marketed under the trade name FIRE STAR™ Rx PTCA Balloon Dilatation Catheter and is indicated for balloon dilatation for the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
P990046/S013 **8/16/07** **180-Day**	ATS Open Pivot™ Bileaflet Heart Valves	ATS Medical, Inc. Minneapolis, MN 55447	Approval for 22/25 mm mitral valves, Models 501DM22, 503DM22 and 500DM25.

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P000039/S021 **8/2/07** **180-Day**	AMPLATZER Septal Occluder	AGA Medical Corporation Golden Valley, MN 55427	Approval for the addition of the 30 mm device size to the "Cribriform" product line.
P010012/S151 **8/24/07** **Real-Time**	CONTAK RENEWAL 3 RF	Guidant Corporation St. Paul, MN 55112	Approval for the following changes to the CONTAK RENEWAL 3 RF models H210, H215, H217, and H219: 1) Digital IC pad change to address premature battery depletion. 2) Hybrid Motherboard DFN trace re-routing from outside layer "4" to an inside layer "3" to reduce electrical field intensity and possible arcing. 3) Trim Target Adjustment.
P040042/S009 **8/21/07** **180-Day**	Safire™ TX Cardiac Ablation Catheter and Interface Cables	Irvine Biomedical, Inc. Irvine, CA 92614	Approval for the Safire™ TX Cardiac Ablation Catheter Model 1642 and the Models 1740-SW and 1779-SE Interface Cables.